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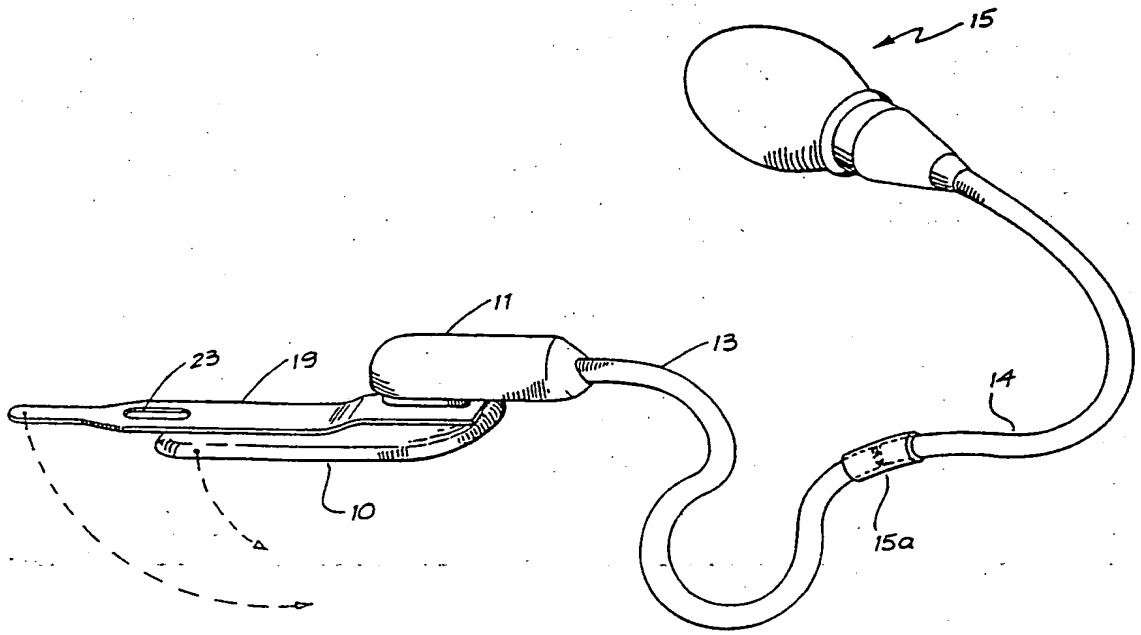

(57) Abstract

A blood flow control system for controlling the amount of blood flowing through an artery to an organ consists of an inflatable occluder (10) that is placed around the artery and an implanted device (15) for actuation of the cuff. The implanted device is in fluid communication (13, 14) with the occluder (10). The amount of blood flow through the artery is controlled by the transcutaneous operation of the implanted device (15). The blood flow control system is particularly suitable for controlling the flow of blood to secondary tumors of the liver by intermittent compression of the hepatic artery as an adjustment to the direct infusion of chemotherapeutic agents. The system can also be used to occlude the splenic artery to treat hypersplenism.

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CONTROL OF BLOOD FLOW TO AN ORGAN

FIELD OF INVENTION

This invention relates to the control of blood flow to an organ of the body.

For the sake of convenience, the invention will, in the main, be described in relation to the control of blood flow through the hepatic artery to the liver. However, it is to be understood that the invention is not limited thereto as it may be readily applied to control the amount of blood flow through the splenic artery to the spleen.

BACKGROUND ART

Both primary and secondary liver tumors are chiefly supplied by blood from the hepatic artery but normal liver tissue derives its blood supply from the portal vein as well as the hepatic artery.

Interruption of the arterial blood supply to the liver and regional infusion of cytotoxic agents have been used as separate and combined treatments for liver malignancies. See, for example, TRANSIENT HEPATIC DEARTERIALIZATION FOLLOWED BY REGIONAL INTRA-ARTERIAL 5-FLUOROURACIL INFUSION AS TREATMENT FOR LIVER TUMORS by Eva P. Dahl et al. Ann. Surg. January, 1981, pages 82-87.

In the Dahl et al study, the hepatic artery was prepared for later temporary occlusion and drug infusion by placing two thin polyethylene slings around the artery, one on each side of the gastroduodenal artery and drawn through separate

larger polyethylene tubes. An infusion catheter was introduced through the right gastropyloric or gastroduodenal artery into the hepatic artery proper.

The slings and catheter were drawn through the abdominal wall via separate stab wounds. After the operation intra-arterial infusion with glucose solution containing heparin and ampicillin was administered daily to keep the hepatic artery open. The arterial occlusion was performed two to five days after the operation by pulling the strangulating slings and securing them with surgical clamps thereby interrupting arterial blood flow. A disadvantage of the polyethylene slings was the need for external control of the occlusion process.

Although it has not been proven that hepatic dearterialisation can prolong the life of liver cancer patents, there is evidence that it will improve the symptoms of liver cancer in some patients with metastic carcinoid disease (see TEMPORARY LIVER DEATERIALIZATION IN PATIENTS WITH METASTATIC CARCINOID DISEASE S. Bengmark, M. Ericsson et al, World J. Surg. 6: 46-53 (1982). There is also evidence that it causes necrosis of tumors (see Bengmark, 1982 above and HEPATIC DEARTERIALIZATION IN CANCER: NEW PERSPECTIVES by S. Bengmark et al Eur. Surg. Res. 18: 1510158 (1986)). Currently the treatment is practised only on a trail basis (not a standard procedure) to be used in combination with chemotherapy.

Permanent hepatic artery ligation and liver

dearterialisation has been tested over many years as noted in the abovementioned articles. The potential advantages of intermittent over permanent dearterialisation are discussed by Bengmark et al (1986) in the article on HEPATIC DEARTERIALISATION IN CANCER: NEW PERSPECTIVES. These advabtages include possibly lower rates of mortality and morbidity and less likelihood of collateral development which is seen as the main reason permanent deartrialisation fails in the long term. A study to compare permanent versus transient occlusion was done in pigs by Persson et al (1984) and suggests that collateral development is less likely if occlusion is transient/intermittent.

The present invention also has application to the control of the amount of blood flowing to the spleen in hypersplenic patients. Such patients typically develop exaggerated hemolytic function of the spleen resulting in deficiency of peripheral blood elements, and hypercellularity of the bone marrow and splenomegaly. Often, the result of this condition is surgical removal of the spleen. The present invention eliminates the need for a splenectomy, and, by reducing the blood flow to the spleen improves its function.

Supporting evidence to the idea that creating splenic ischaemia, thereby partially destroying the spleen, may be used to treat hypersplenism (e.g. due to thalassaemia or portal hypertension) is to be found in PARTIAL SPLENIC EMBOLISATION FOR HYPERSPLENISM OF THALASSAEMIA MAJOR: FIVE

YEAR FOLLOW UP, British Medical Journal 294: 665-667 (1987) and ISCHAEMIA AND PARTIAL RESECTION FOR CONTROL OF SPLENIC HYPERFUNCTION by C.L. Witte et al Brit. Surg. 6a: 531-535 (1982). According to these papers, the spleen was successfully destroyed by embolisation and partial spelectomy. The same end could be reached by intermittently occluding the splenic artery for a prolonged period

DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide an improved means for controlling the flow of blood to an organ of the body which does not incorporate any control means that physically penetrates the body's surface (skin) and therby lessens the risk of infection.

According to the invention, there is provided a blood flow control system for controlling the flow of blood from an artery to an organ, said system comprising an inflatable occluder adapted to be coupled to the artery and an implant device for the actuation and deactivation of the occluder adapted to be positioned beneath the skin but operable by means applied externally to the body.

Preferably, the inflatable occluder consists of a flexible elastic bag placed around the hepatic artery which is in fluid communication with an actuation device placed completely beneath the skin.

In one form of the invention, the actuation device is a manually compressible reservoir-balloon located beneath the skin but easily operated by externally applied pressure. A

release valve which prevents fluid back-flow into the reservoir balloon is located adjacent to the reservoir balloon and is also operated and opened by externally applied pressure.

Compression of the reservoir balloon through the skin causes inflation of the occluder around the hepatic artery thereby occluding the artery. The nature of the release valve adjacent to the reservoir balloon prevents the fluid from flowing back into the reservoir balloon. Activation of the release valve allows immediate reflux of the fluid into the reservoir balloon beneath the skin and deflation of the occluder inserted around the artery. The fluid is forced back into the reservoir balloon by the blood pressure acting on the occluder and due to the suction caused by the elastic recoil force of the compressible reservoir balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the invention may be more readily understood and put into practical effect, reference will now be made to the accompanying drawings in which:-

Fig. 1 is a perspective view of an implantable device for controlling and flow of blood according to one embodiment of the invention,

Fig. 2 is a cross-sectional view of an implantable device shown in Fig. 1,

Fig. 3 is a schematic diagram of a first fistula arrangement used in the example of the invention,

Fig. 4 is a schematic diagram of a second fistula

arrangement used in the example of the invention, and,

Fig. 5 is a schematic diagram of a third fistula arrangement used in the example of the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

The blood flow control device shown in Fig. 1 and 2 includes an inflatable pressure means or cuff 10 mounted on a connector 11 having a passage-way 12 in communication with the interior of the occluder cuff 10 and a connecting tube 13. A coupling 15a connects connecting tube 13 to connecting tube 14.

The other end of the connecting tube 14 is connected to a pump assembly 15 which includes a compressible reservoir 16, a valve 17 and a valve body 18.

A strap 19 is connected to the connector 11 above the cuff 10 and has an aperture 23 through which is fed the connecting tube 13 and the connector 11 so that the strap can be locked to the connector 11 after it has encircled the vein.

The valve 17 of Fig. 2 has a body of silicone or other implantable flexible material which defines a valve chamber 18. The valve inlet is connected to the reservoir 16. The outlet 20 (which is closed by diaphragm 24) is connected to the inflatable occluder cuff 10.

In operation, fluid from the reservoir 16 can be forced into the inlet 25 and through the bore of valve 17 where its pressure lifts the valve diaphragm 24 so that the fluid can

pass through the outlet 20. As soon as pressure on the reservoir is relaxed, the diaphragm 24 returns to its original position in which it seals against the valve seat.

When fluid is to be returned to the reservoir, the valve body is squeezed in the direction of arrows A to lift the diaphragm 24 so that the fluid can return to reservoir 16

The blood flow control system of the invention is particularly suitable to control the blood flow to secondary tumors of the liver by intermittent compression of the hepatic artery as an adjunct to the direct infusion of chemotherapeutic agents by infusing either the portal vein or the hepatic artery through any convenient delivery system such as "Infusaport". The timing of the dearterialisation and drug infusion is variable dependent on the size of the tumor and its origin.

EXAMPLE

The aim of this study was to determine the effect of implanting a silicone cuff arund a vein which was made hypertensive by an arteriovenous fistula.

The inflatable silicone cuffs were injection moulded from medical grade liquid silicone rubber (SILASTIC (Reg. T.M.) Q7-4780, Dow Corning Corp.). The cuffs were 1.5cm wide. The strap on the outside of the inflatable cuff was made from DACRON (Reg. T.M.) reinforced medical grade silicone rubber (SILASTIC, Dow Corning Corp. Catalog NO. 501-3). These cuffs were inflatable by a bulb which is implanted in the nearby neck subcutaneously. The cuffs can be inflated

(after closure of the skin) transcutaneously. The cuff end of the device was the only part of the device in contact with the vein. A reservoir which is used to inflate the cuff was implanted elsewhere in the neck.

Two surgical procedures were used. In the first procedure, an arteriovenous fistula was created to produce a hypertensive vein in sheep using a 6-0 continuous Prolene suture technique. A circumferential inflatable cuff was placed around the vein proximal to the fistula to produce mild constriction. The wound was then closed and the sheep left to recover.

Five different types of fistulae arrangements were usedas the model was being developed. The side to side fistula was ultimately chosen as the most appropriate due to ease of the procedure, it is less traumatic and high venous pressures are obtained.

In Type 1, a side-to-side fistula was created between the superficial femoral vein and the femoral artery of 2 sheep (nos. 27 and 28). The vein distal to the fistula was ligated to further increase intraluminal pressure.

In Type 2, a side-to-side arteriovenous anastamosis was created between the internal jugular vein and the common carotid artery of 7 sheep (nos. 29, 30, 31, 32, 33, 35 and 42). The vein distal to the fistula was ligated to further inrease intraluminal pressure.

In Type 3, the arrangement was identical to the second arrangment just mentioned and was applied to 2 sheep (nos. 37

and 41). In addition, the cuff was inflated 20 minutes a day, 6 days a week to maximally stress the vein.

Fig. 3 illustrates the first three fistulae arrangements used in the animal model of venous hypertension. Not shown is the fact that the distal vein was ligated in this study. Although Fig. 3 shows the internal jugular vein and common carotid artery, the type 1 arrangement was identical except that different vessels are used. The type 2 and type 3 arrangements differed only that in the type 3 arrangement, the cuff was periodically inflated.

In Type 4, a cross-over fistula arrangement was used with 1 sheep (no. 62). The opposite jugular vein was mobilised and anastamosed end to side to the internal jugular vein. The internal carotid artery of the side under study was anastamosed end to side to this internal jugular vein. This arrangement is shown in Fig. 4.

In the Type 5 arrangement, the fistula was created using a DACRON (Registered T.M.) "H" graft using an end to side anastamosis from the graft to the internal carotid artery to the internal jugular vein on 1 sheep (no. 68). This arrangement is shown in Fig. 5.

When each of the above five fistulae was created, the wound was closed and the sheep left to recover. At the second procedure, the veins were harvested at varying times following the first operation.

The veins were examined macroscopically to determine any alterations. Specimens were taken for histological

examination in all sheep. Specimens were also taken as controls 3 cm proximal or distal to the implant as indicated in Table 2 which gives the detailed results.

These specimens were examined histologically by an independent histologist who was not notified as to whether the speciment was from under a silicone implant or a control specimen. The method of reporting was to score each specimen as to the severity of possible responses to the implantation of a silicone cuff. The scores were:

0 - nil

1 - minimal

2 - moderate

3 - severe

4 - Complete

The categories scored were:

- Fibrosis of the intima, media and the adventitia
- Extracellular Hyalinisation
- Intimal Thickness
- Sub-intimal Neovascularisation
- Endothelial Denudation
- Giant Cell Response
- Fragmentation of the Internal ELastic Lamina

Thirteen sheep were studied under this experiment and the results are given in Table 1. The implants were left in situ for an average of 17 weeks with a range of 4 - 32 weeks. All veins dilated so that the least diameter was at

the site of the cuff. Pressure measurements were performed in three cases with the pressure being 40 - 60 mm Hg.

Macroscopic findings did not reveal any case in which there was thrombosis, fibrous obstruction or ulceration. The vein wall was generally very dilated as a consequence of the high fistula pressures. The vein wall under the silicone was smooth with no ulceration and minimal thickening. A fibrous sheath was always present.

The histology of the vein wall was very similar to that of the distal control specimens. There was mild fibrosis with hyalinisation and moderate sub-intimal neovascularisation. There was however, generally a more severe fragmentation of the internal elastic lamina as in the previous study. There was minimal endothelial denudation in most sheep but this was present in sheep 28, 29, 6 and 68.

Scanning Electron Microscopy was performed on sheep Nos. 30, 37, 41 and 62. The specimens from under the implants showed the endothelium mostly intact with fibrin deposition in sheep Nos. 41 and 37 which were from sheep in which periodic compression was performed. The only abnormality in the other specimens was some surface pitting in sheep No. 62. There was one wound infection in sheep 42 for which the device was removed.

This study was instituted to mimic the high venous pressures present in patients with venous hypertension. These pressures reach at least 60 mm Hg. The inevitable dilatation of the fistula means that the narrowest part of

the vein is the segment with the silicone cuff. This mimics the implantation of the cuff in the human situation where the valve ring must be narrowed to make the valve competent. The surrounding vein will be a greater diameter due to dilatation. The endothelial damage does not appear to be a significant problem as there was no case of ulceration, thrombosis or fibrous stricture at this area or at any other site. The histological damage was in close proximity to the arterio-venous anastomosis and was possibly related to the high pressure and turbulence at this site. The changes appear to be due to a repair process following dissection and from the damage caused by the fistula. Comparison of the implant and control specimens from light microscopy (Table 2) shows that the majority of the changes were not due to implantation of the venous cuff. Similar changes are seen even without an implant (sheep 92 in protocol 22/1) and have been described in more severe form in vein grafts (28, 94, 102).

Partially and even severely constricting silicone implants placed around fistularised veins with continuous high pressure are safe and do not cause constricting fibrosis or thrombosis.

These results show that the silicone cuff can be placed around vessels with high pressure inside with safety. The cuff can also be intermittently inflated with minimal problems. There was no problem with thrombosis or stenosis.

Various modifications may be made to the system without departing from the scope and ambit of the invention.

Table 1 - Summary of Results of Implanting Silicone Cuffs around Hypertensive Veins

Sheep No.	Side of Implant	Type of Fistula	Date of Implant	Date of Harvest	Duration of Implant	Light Microscopy of Implant	Light Microscopy of Controls	SEM of Implants	SEM of Controls	Complications
27	Left	1	15/4/85	15/7/85	13 weeks	Fibrosis of media and adventitia. Moderate intimal thickness	Moderate fibrosis of adventitia.	Not Applicable	Not Applicable	Nil
28	Left	1	30/5/85	29/7/85	9 weeks	Minimal fibrosis adventitia. Endothelial denudation	Not Applicable	Not Applicable	Not Applicable	Nil
29	Left	2	3/6/85	12/9/85	14 weeks	Moderate fibrosis adventitia. Intimal thickening	Not Applicable	Not Applicable	Not Applicable	NIL
30	Left	2	20/6/85	23/9/85	14 weeks	Moderate intimal thickening	Not Applicable	Normal	Normal	Nil
31	Right	2	24/6/85	16/9/85	12 weeks	Fibrosis of media and adventitia	Not Applicable	Not Applicable	Not Applicable	Nil

Table 1 continued

32	Right	2	1/7/85	25/11/85	21 weeks	Minimal abnormality	Minimal abnormality	Not Applic-able	Not Applic-able	Nil
33	Right	2	4/7/85	9/12/85	23 weeks	Normal	Normal	Not Applic-able	Not Applic-able	Nil
35	Right	2	1/8/85	19/3/86	32 weeks	Minimal abnormality	Minimal abnormality	Not Applic-able	Not Applic-able	Nil
42	Right	2	14/11/85	12/12/85	4 weeks	Normal	Fibrosis of vein wall	Not Applic-able	Not Applic-able	Wound infection Device removal
37	Right	3	10/10/85	2/5/86	29 weeks	Minimal abnormality	Minimal abnormality	Fibrin depo-sition	Not Applic-able	Nil
41	Right	3	11/11/85	2/3/86	16 weeks	Fibrosis of adventitia	Minimal abnormality	Some fibrin deposit. Denudation	Some fibrin deposit.	Nil
52	Right	4	5/6/86	27/10/86	20 weeks	Minimal fibrosis. Endothelium denudation.	Not Applic-able	Pitting	Normal	Nil

Table 1 continued

58	Right	5	14/7/86	3/11/86	16 weeks	Fibrosis of adventitia. Endothelium denudation.	Fibrosis of vein wall. Minimal endothelium denudation.	Not Applic-able	Not Applic-able	Nil

Type of Fistula:

1. Femoral artery to femoral vein side to side anastamosis. Distal vein ligated.
2. Carotid artery to jugular vein side anastamosis. Distal vein ligated.
3. Identical to type 2. In addition, the inflatable cuff was inflated 20 minutes a day, 6 days a week.
4. Cross over fistula used rather than side to side anastamosis.
5. Dacron "H" graft from carotid artery to jugular vein.

Table 2 - LIGHT MICROSCOPIC OBSERVATIONS OF SILICONE CUFF IMPLANTS SURROUNDING HYPERTENSIVE VEINS

Sheep No.	Specimen *	Duration of Implant	Fibrosis Intimal	Fibrosis Media	Fibrosis Adventitia	Extracellular Hyalinisation	Intimal Thickness	Sub-initmal Neovascularisation	Endothelial Denudation	Giant Cell Response	Fragmentation Internal Elastic Lamina
27	Implant	13 weeks	1	3	3	2	2	3	1	1	2
	Control (D)		0	1	2	1	0	2	1	0	0
28	Implant	9 weeks	0	0	1	2	0	1	4	0	4
29	Implant	14 weeks	0	0	2	1	3	3	4	0	4
30	Implant	14 weeks	0	0	0	2	2	3	0	0	2
31	Implant	12 weeks	0	2	3	2	0	2	1	0	2
	Control (D)		0	2	3	2	0	1	2	0	1
32	Implant	21 weeks	0	1	1	-	-	-	0	0	-
	Control (D)		0	1	1	-	-	-	0	0	-
33	Implant	23 weeks	0	0	0	-	-	-	0	0	-
	Control (D)		0	0	0	-	-	-	0	0	-
35	Implant	32 weeks	0	1	2	-	-	-	0	0	-
	Control (D)		0	1	0	-	-	-	0	0	-
	Control (P)		0	0	0	-	-	-	0	0	-

Table 2 (cont.)

Sheep No.	Specimen *	Duration of Implant	Fibrosis Intimal	Fibrosis Media	Fibrosis Adventitia	Extracellular Hyalinisation	Intimal Thickness	Sub-initmal Neovascularisation	Endothelial Denudation	Giant Cell Response	Fragmentation Internal Elastic Lamina
42	Implant	4 weeks	0	0	0	-	-	-	0	0	-
	Contr 1 (D)		2	2	3	-	-	-	0	4	-
37	Implant	29 weeks	0	0	0	1	0	1	1	0	4
	Control (D)		0	0	1	1	0	1	1	0	2
	Control (P)		0	0	0	1	2	1	0	0	0
52	Implant	20 weeks	1	1	1	3	1	3	4	0	3
68	Implant	16 weeks	0	1	2	3	2	2	3	0	2
	Control (D)		2	2	3	3	2	3	1	0	2
Average											
	Implant	17 weeks	0	1	1	2	1	2	1	0	3
	Control (D)		0	1	1	2	0	2	1	1	1
	Control (P)		0	0	0	1	1	1	0	0	0

* D = distal; P = poximal to implant.

CLAIMS

1. A blood flow control system for controlling the flow of blood from an artery to an organ, said system comprising an inflatable occluder adapted to be coupled to the artery and an implant device for the actuation and deactivation of the occluder adapted to be positioned beneath the skin but operable by means applied externally to the body.

2. A blood flow control system according to claim 1 wherein the inflatable occluder consists of a flexible elastic bag placed around the hepatic artery which is in fluid communication with an actuation device placed completely beneath the skin.

3. A blood flow control system according to claim 1 or claim 2 wherein the actuation device is a manually compressible reservoir located beneath the skin but easily operated by externally applied pressure.

4. A blood flow control system according to any one of the preceding claims and including a release valve which prevents fluid back-flow into the reservoir located adjacent to the reservoir and also operated and opened by externally applied pressure.

5. A method of controlling the flow of blood from an artery to an organ said method comprising the steps of:

a) placing an inflatable occluder around the artery,

b) implanting a device for actuating the occluder beneath the skin, and,

c) controlling the amount of blood flow through the artery to the organ by transcutaneously actuating the implanted device so as to inflate and deflate the occluder.

6. A method of effecting hepatic dearterialisation comprising the steps of placing an inflatable occluder cuff around the hepatic artery, implanting beneath the skin a device for actuating the occluder, and connecting the cuff to the actuating device whereby the amount of blood flow through the hepatic artery can be controlled by transcutaneously actuating the implanted device to inflate and deflate the occluder without the need for invasive surgery.

7. A method of intermittently occluding the splenic artery for a predetermined period including the steps of placing an inflatable occluder cuff around the splenic artery, implanting beneath the skin a device for actuating the occluder, and connecting the cuff to the actuating device whereby the amount of blood flow through the splenic artery can be controlled by transcutaneously actuating the implanted device to inflate and deflate the occluder without the need for invasive surgery.

8. A method according to any one of claims 5 to 7 using a blood flow control system as claimed in any one of claims 1 to 4.

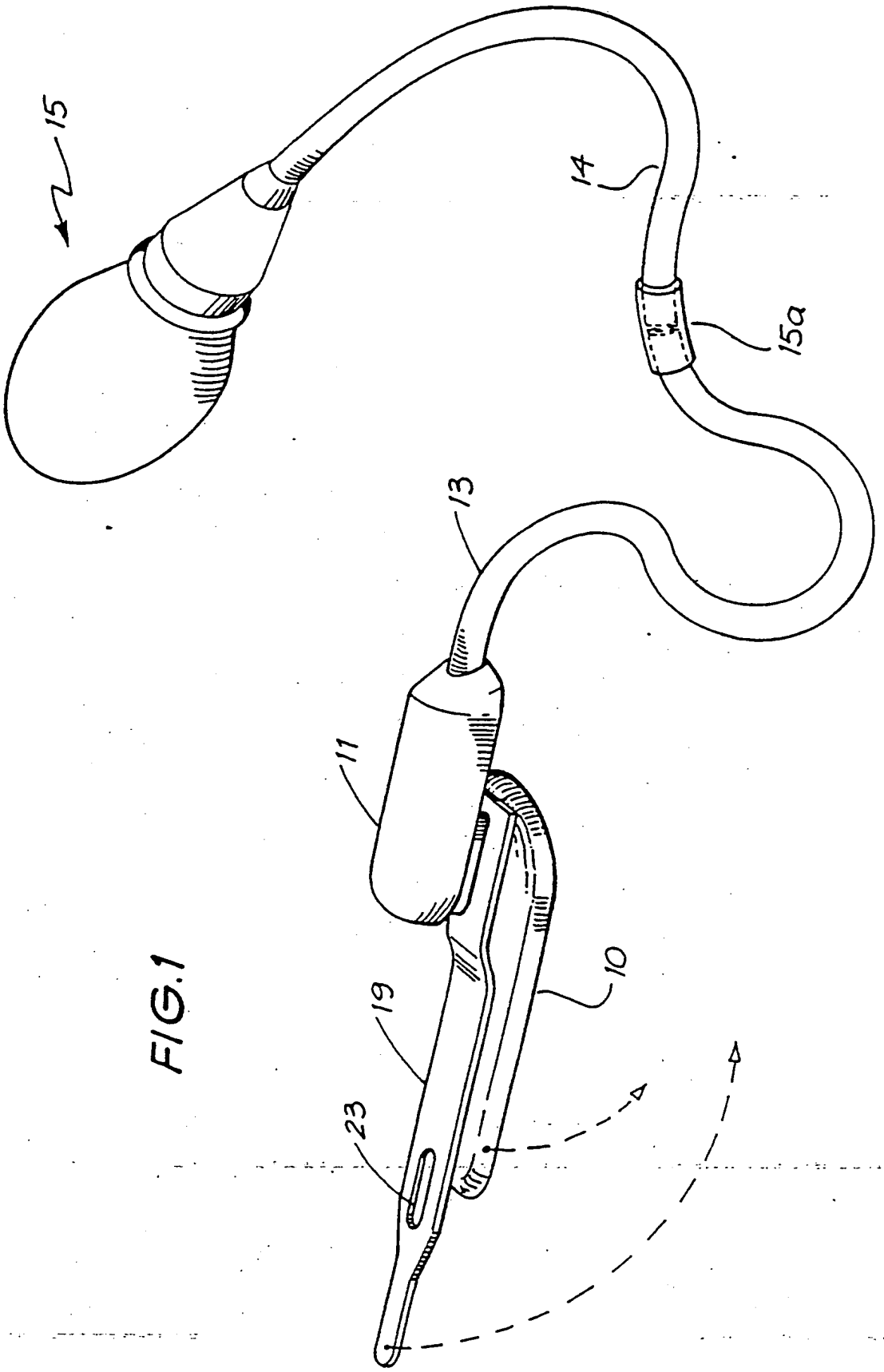

FIG.1

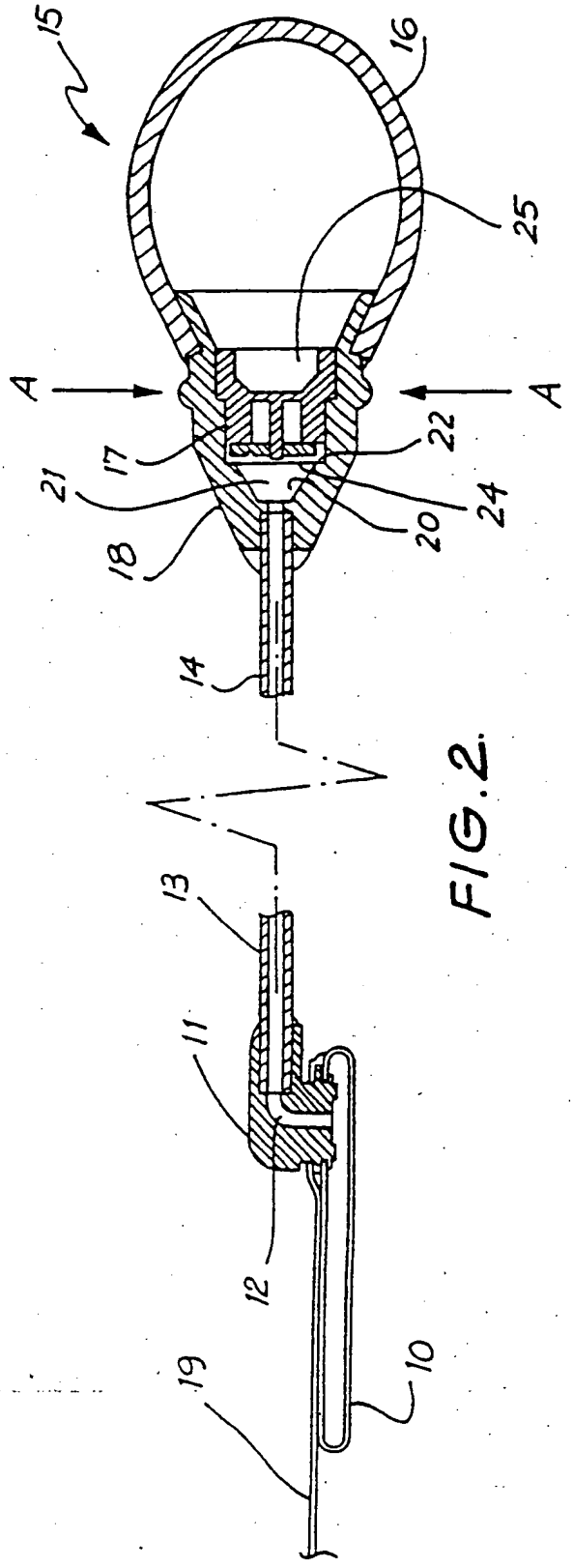

FIG.2.

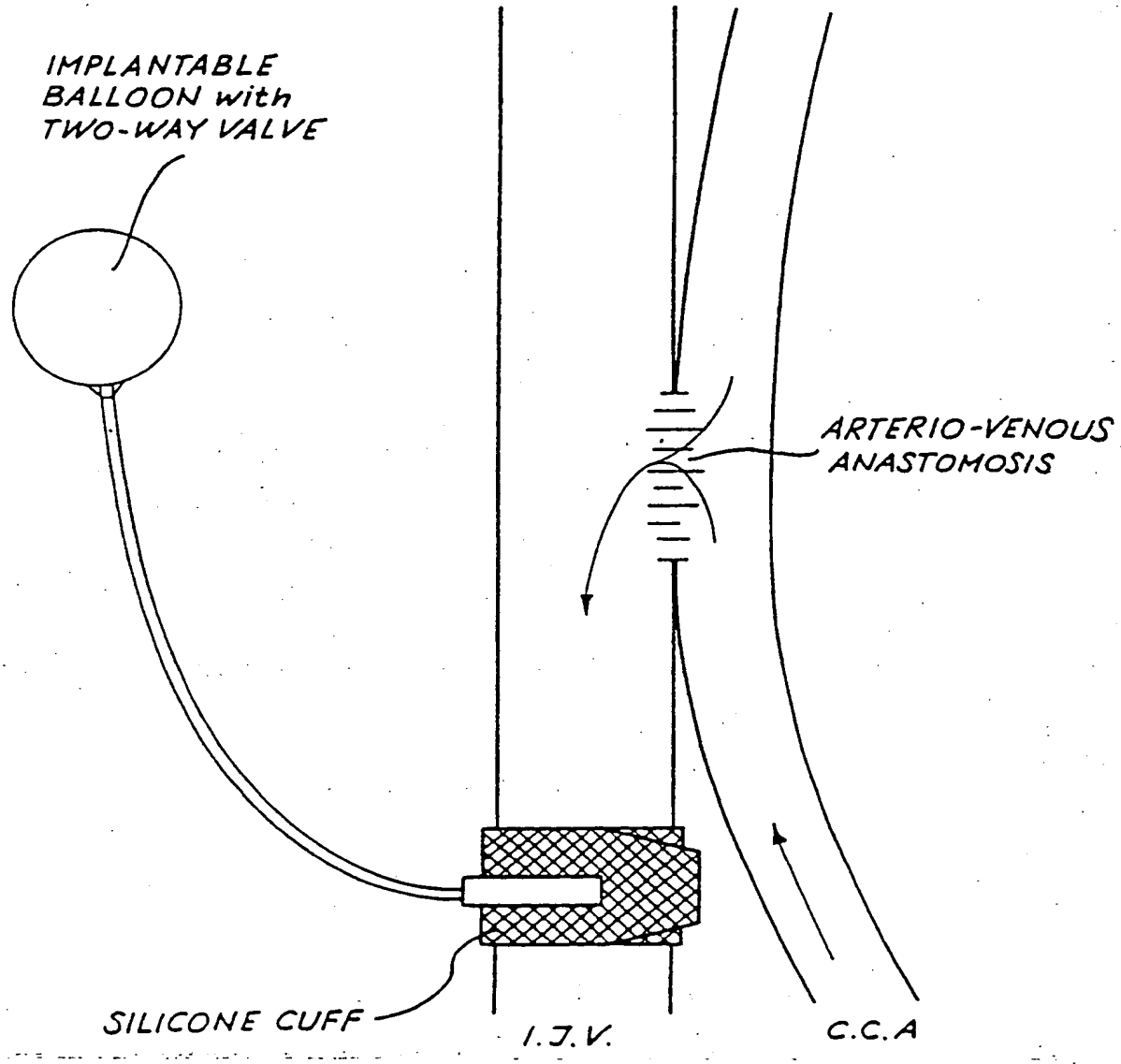

FIG. 3

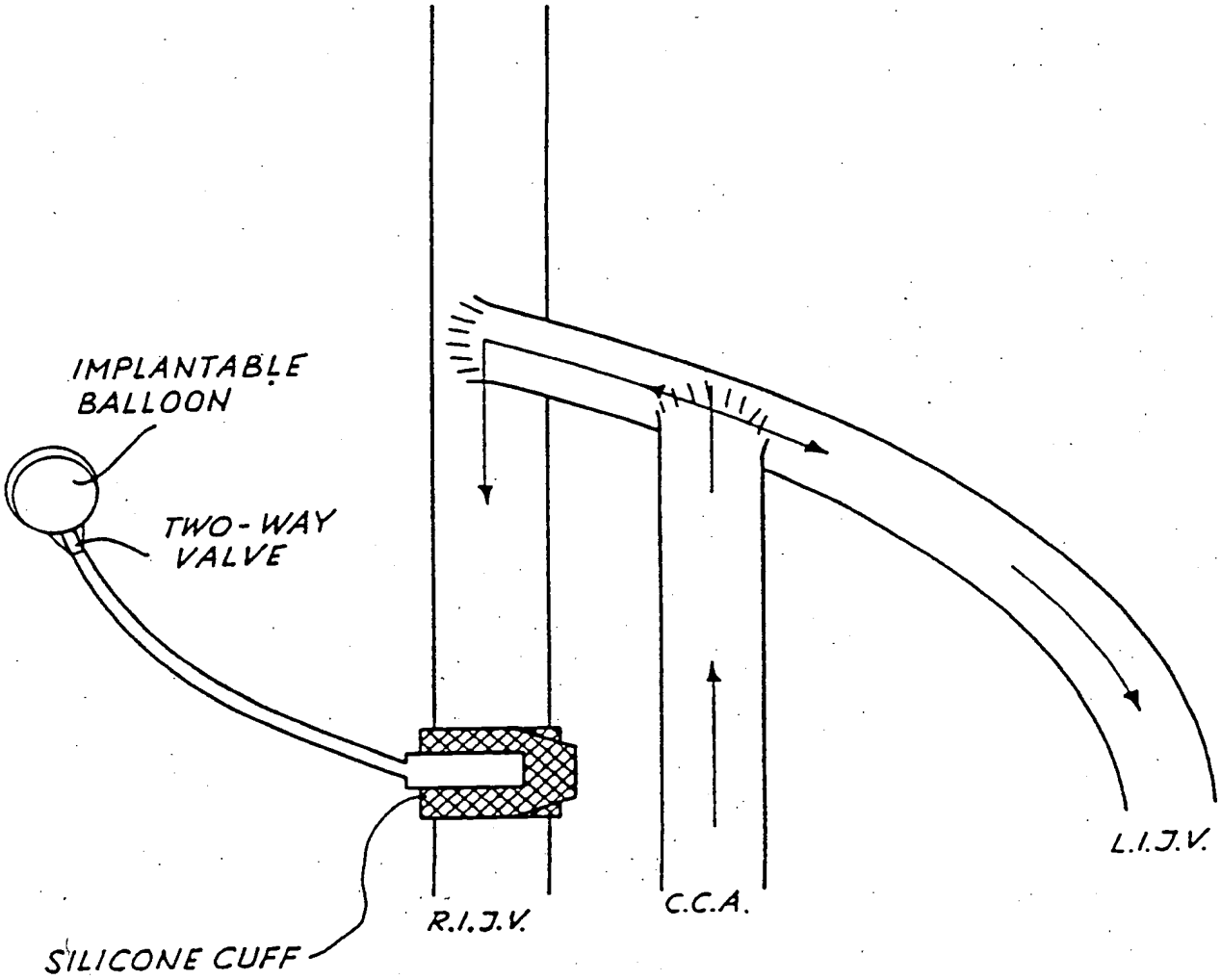
IMPLANTABLE BALLOON
TWO-WAY VALVE
SILICONE CUFF
R.I.J.V.
C.C.A.
L.I.J.V.

FIG. 4

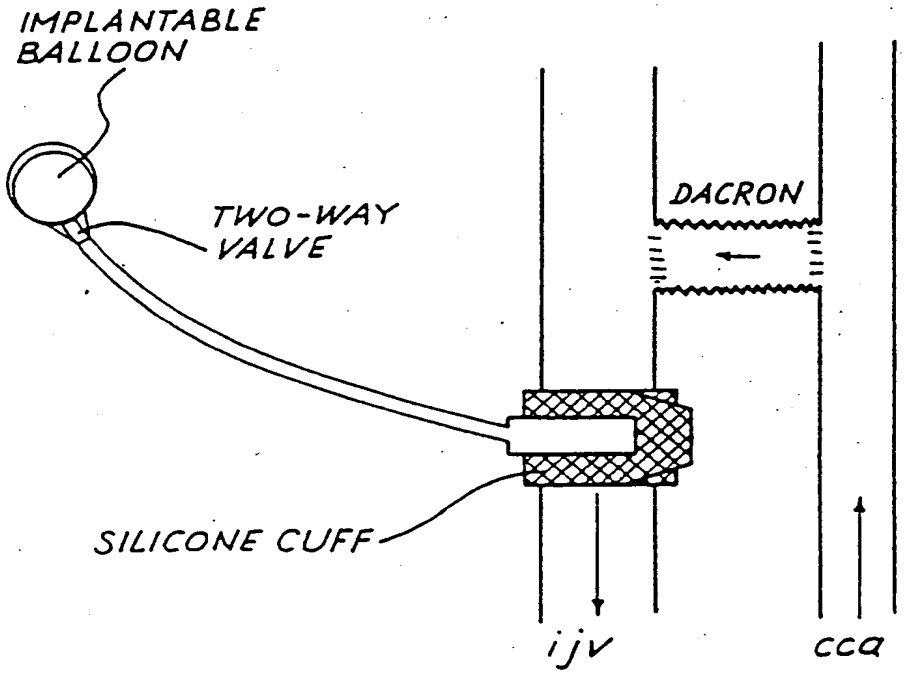

FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 87/00225

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[4] A61B 17/12

II. FIELDS SEARCHED

Minimum Documentation Searched †

Classification System	Classification Symbols
IPC	A61B 17/12, A61F 2/48, A61F 1/00

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched ‡

AU : IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT §

Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages ††	Relevant to Claim No. ††
X	US,A, 3730186 (EDMUNDS, Jr. et al) 1 May 1973 (01.05.73) See column 4 line 60 to column 5 line 4, Claim 1, abstract and Figure.	1-3,5-8
A	GB,A, 1268034 (DUNN) 22 March 1972 (22.03.72)	1
A	US,A, 4478219 ROZARIO et al) 23 October 1984 (23.10.84)	1
A	US,A, 3538917 (SELKER) 10 November 1970 (10.11.70)	1
A	US,A, 4531519 (DUNN et al) 30 July 1985 (30.07.85)	1

* Special categories of cited documents: ††

"A" document defining the general state of the art which is not considered to be of particular relevance

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"&" document member of the same patent family

IV CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
2 November 1987 (02.11.87)	(06.11.87) 6 NOVEMBER 1987
International Searching Authority: Australian Patent Office	Signature of Authorized Officer: E.N. PERRIS

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 87/00225

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Members
US 3730186	US 3831583
US 4478219	AU 15103/83 EP 104246 WO 8303345
US 4531519	AU 59485/80 BR 8003837 CA 1172124 DK 2655/80 EP 21804 GB 2053690 IL 60336 IN 153202 JP 56027243 ZA 8003521

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